PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Impact of tailored falls prevention education for older adults at hospital discharge on engagement in falls prevention strategies post discharge: protocol for a process evaluation.
AUTHORS	Naseri, Chiara; McPhail, Steven; Netto, Julie; Haines, Terrence; Morris, Meg; Etherton-Beer, Christopher; Flicker, Leon; Lee, Den-Ching; Francis-Coad, Jacqueline; Hill, Anne-Marie

VERSION 1 – REVIEW

REVIEWER	Patricia Dykes Brigham and Women's Hospital Harvard Medical School Boston, MA
REVIEW RETURNED	11-Dec-2017

GENERAL COMMENTS	The purpose of this mixed methods process evaluation is to determine if a fall prevention educational intervention has the intended effect on the intermediate outcome of older adults' engagement in falls prevention strategies after discharge. The evaluation is nested within a fall prevention RCT and if successful will provide a better understanding of the effect of the intervention on fall rates in that clinical trial. • Primary aim: to evaluate the impact of tailored falls prevention discharge education (in addition to usual care), on engagement in falls prevention strategies in the six months post discharge vs. usual care alone. • Secondary aims: to evaluate capability and motivation to engage in falls prevention strategies for those participants who received tailored falls prevention education in addition to usual care, compared to those that received a social intervention in addition to usual care; and b) to explore the barriers and facilitators to engaging in falls prevention strategies and to identify the social and physical environment opportunity that are supportive of fall prevention strategies The mixed methods evaluation proposed is a strength of the study design and will facilitate a comprehensive understanding of the intervention's effectiveness on older adult engagement in falls prevention strategies as well as the barriers, facilitators, and context surrounding their level of participation. The manuscript is well written, addresses an important problem, and will be of interest to BMJ Open readers. The authors are to be commended on their detailed methods to measure patient engagement. There are a few issues that require clarification. I realize that a description of the intervention was published earlier but there should be sufficient information in this manuscript to

	understand the intervention and how it is being evaluated. • The 'social intervention' identified in the secondary aims is not defined and is not mentioned in the description of the intervention, methods, or analysis. • The risk factors for falls in community dwelling older persons are well understood. What is the rationale for only addressing a subset of modifiable risk factors in the educational intervention? For example, baseline data on vision is collected, yet the educational intervention does not address vision, even though some aspects are modifiable (i.e., teaching patients not to walk with bifocal lenses, using bright colored tape on stairs to improve depth-perception, encouraging regular eye exams). Orthostatic hypotension is another common cause of falls in older persons and there are some things that older people can do to modify this risk factor (slow, purposefuly position changes, ensuring adequate hydration, wearing compression stockings). Not addressing these risk factors as part of the educational interventions seems to be a missed opportunity and limitation of the intervention. • The types of exercise that are known to reduce risk fall falls relate to gait, strength and balance training/exercise programs. How will these types of programs be differentiated from other exercise that is not associated with reduced risk? • Are the training sessions 45 minutes each session, or a total of 45 minutes? If the former, is it feasible to conduct up to 180 minutes of fall prevention education with a single patient prior to discharge? How will you control for the amount of falls prevention education each patient received (e.g., the dose of the intervention)? • Authors mention that they will cross check self-reported data with baseline data including data from medical files. What data elements will be compared and what methods will be used for this analysis?

REVIEWER	Maw Pin Tan University of Malaya, Malaysia
REVIEW RETURNED	02-Feb-2018

GENERAL COMMENTS	General Comments The authors presented the study protocol for a randomised controlled trial (RCT) which plans to evaluate the effectiveness of a falls prevention education on the participants engagement in fall prevention strategies. This RCT was described as a nested RCT from a larger RCT which has been registered as a clinical trial and the protocol has also been published separately. The area of study is of major importance, and the authors are exploring particular issues rarely addressed by previous falls intervention study by conducting a mixed-method evaluation for study outcomes. Specific Comments: Title: The authors that this was a process evaluation, presumably because it was supposedly nested within the a larger RCT which measured falls outcomes. However, the objectives did not appear to match the title. Perhaps the title should be along the lines of "impact of tailored falls prevention education on engagement in falls prevention strategies post-discharge. Abstract:

	This was well written presented clearly. Main text: Introduction- This was again well written and sets the scene well for the entire study. However, one can't help but wonder that, when you get to the discussion, whether the authors had put too much into the introduction and left too little in the discussion. Perhaps some of the description of the COM-B theory etc perhaps should be better placed in the discussion section. Methods: The trial has been supposedly registered under the "Best to My Best study". The clinical trial registration states that the study started in mid 2015 and recruitment ended in October 2017. Have the authors only chosen to publish the protocol after the completion of the study, or has recruitment been extended? The authors also suggested that this was a nested RCT. However, as this RCT seems to have the same number of subjects as the main RCT, was this study actually one evaluating the secondary outcome measures, or an extension of the initial intervention study. The proposed mixed method analysis of the does not seem to have been submitted with the trial registration. If the authors have amended the original proposals to ethics. the registered protocol may need to be amended within the Clinical Trial Registry. Discussion The first two lines of the discussion represent repetition. The limitations paragraph: It is unclear what is meant by primary and secondary data will not be collected until six months post-discharge. References This protocol paper is perhaps over-referenced. 73 references for a protocol paper may be a little excessive. The authors may wish to reduce the number of references they include in their manusript. Some of the references are a little dated.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1

The mixed methods evaluation proposed is a strength of the study design and will facilitate a comprehensive understanding of the intervention's effectiveness on older adult engagement in falls prevention strategies as well as the barriers, facilitators, and context surrounding their level of participation.

The manuscript is well written, addresses an important problem, and will be of interest to BMJ Open readers. The authors are to be commended on their detailed methods to measure patient engagement. There are a few issues that require clarification. I realize that a description of the intervention was published earlier but there should be sufficient information in this manuscript to understand the intervention and how it is being evaluated.

- **Response:** Thank you for your valuable comments and feedback, please find Author's responses below.

The 'social intervention' identified in the secondary aims is not defined and is not mentioned in the description of the intervention, methods, or analysis.

- **Response:** Thank you for this clarification. We have added further text to define the Education Intervention, Control/Social Intervention and the Usual care. This can be found in the Methods section, Education intervention, paragraph 2, page 10.

The risk factors for falls in community dwelling older persons are well understood. What is the rationale for only addressing a subset of modifiable risk factors in the educational intervention? For example, baseline data on vision is collected, yet the educational intervention does not address vision, even though some aspects are modifiable (i.e., teaching patients not to walk with bifocal lenses, using bright colored tape on stairs to improve depth-perception, encouraging regular eye exams). Orthostatic hypotension is another common cause of falls in older persons and there are some things that older people can do to modify this risk factor (slow, purposefully position changes, ensuring adequate hydration, wearing compression stockings). Not addressing these risk factors as part of the educational interventions seems to be a missed opportunity and limitation of the intervention.

- **Response:** The intervention is designed to address key issues that could affect older people in the post discharge period. Participants will continue to receive usual care from their medical team which could include these types of interventions. We are not able to describe the effect of this type of intervention which seeks to address the post discharge period at present, but we take this comment for future analysis, and the process evaluation should assist in explaining whether more tailoring is required.

The types of exercise that are known to reduce risk fall falls relate to gait, strength and balance training/exercise programs. How will these types of programs be differentiated from other exercise that is not associated with reduced risk?

- **Response:** Thank you for your clarification. We have added text to include the types of exercise that will be recorded ("such as a strength and balance exercise program, group exercise, swimming, golf, tai chi, walking, dancing, the frequency, duration, whether supervised, location (home or centre), and whether a balance component is included will also be recorded.") This can be found in the Methods/Outcome measures/ Quantitative outcomes, point iii), page 11.

Are the training sessions 45 minutes each session, or a total of 45 minutes? If the former, is it feasible to conduct up to 180 minutes of fall prevention education with a single patient prior to discharge? How will you control for the amount of falls prevention education each patient received (e.g., the dose of the intervention)?

- **Response:** Thank you for your clarification, we have amended the text to read that the intervention is planned to be a total of 45 minutes, this will be recorded by the researchers separately delivering the interventions. The amount of education that people receive will be used during sensitivity analysis to assist to explain participants' knowledge, motivation, and engagement in falls prevention strategies after discharge. This will be done using a regression with adjustment for potential co-variates including the education dose (Methods/Outcomes measures section, last paragraph, page 13).

Authors mention that they will cross check self-reported data with baseline data including data from medical files. What data elements will be compared and what methods will be used for this analysis?

- **Response**: We appreciate the reviewer drawing this section of text to our attention. This was written in error during an earlier version circulated among some of the investigators as we discussed this issue, and given that we are not able to feasibly verify / cross-check self-reported information (e.g., regarding whether they felt motivated to engage with exercise in the community), we elected to instead acknowledge the self-reported nature of this information as a limitation (although erroneous phrase regarding cross-checking with multiple data sources remained in our original submission). We have now amended this section of text to clarify that the self-reported nature of this data is considered a limitation of this study (and removed the erroneous section of text).

Reviewer: 2

Reviewer Name - Maw Pin Tan

Institution and Country

University of Malaya, Malaysia

Please leave your comments for the authors below

General Comments

The authors presented the study protocol for a randomised controlled trial (RCT) which plans to evaluate the effectiveness of a falls prevention education on the participants engagement in fall prevention strategies. This RCT was described as a nested RCT from a larger RCT which has been registered as a clinical trial and the protocol has also been published separately. The area of study is of major importance, and the authors are exploring particular issues rarely addressed by previous falls intervention study by conducting a mixed-method evaluation for study outcomes.

- **Response:** Thank you for your valuable comments and feedback, please find Author's responses below. Authors have corrected this description to reflect that this study not a nested RCT within the clinical trial, but rather a process evaluation of the education intervention. We have clarified this in text – see below responses.

Specific Comments:

Title: The authors that this was a process evaluation, presumably because it was supposedly nested within the a larger RCT which measured falls outcomes. However, the objectives did not appear to match the title. Perhaps the title should be along the lines of "impact of tailored falls prevention education on engagement in falls prevention strategies post-discharge.

- **Response:** Thank you we have slightly amended the title as per suggestion.

Abstract:

This was well written presented clearly.

Main text:

Introduction- This was again well written and sets the scene well for the entire study. However, one can't help but wonder that, when you get to the discussion, whether the authors had put too much into the introduction and left too little in the discussion. Perhaps some of the description of the COM-B theory etc perhaps should be better placed in the discussion section.

- **Response:** Thank you for your suggestion, we have shifted some text from the Introduction to the Discussion section, paragraph 2-4, page 17.

Methods: The trial has been supposedly registered under the "Best to My Best study". The clinical trial registration states that the study started in mid -2015 and recruitment ended in October 2017. Have the authors only chosen to publish the protocol after the completion of the study, or has recruitment been extended?

- **Response:** Thank you for prompting us to clarify this point, as we did not phrase this clearly in the original submission. This is a mixed method process evaluation of the interventions delivered in the "Back to my Best trial" that is currently ongoing. This trial has not yet been completed and has this process evaluation protocol has been submitted in compliance with the BMJ Open instructions for authors for study protocols. This process evaluation manuscript was submitted to BMJ open on 20th November 2017, but the peer review process has meant it is now being published at this later date, but even at this later date data collection is still ongoing. The process evaluation follows participants that were included in the randomised trial. There is a 6 month follow up period which is now underway and should finish in April. After this some qualitative work will still being undertaken with trial participants (most likely to finish in approximately May 2018). The primary protocol for the RCT was published in BMJ Open: doi:10.1136/bmjopen-2016-. In that manuscript we reported that the process evaluation protocol would be submitted at a later time, and this is the aforementioned process evaluation protocol. To be very clear, we are not publishing this after the completion of the study.

The authors also suggested that this was a nested RCT. However, as this RCT seems to have the same number of subjects as the main RCT, was this study actually one evaluating the secondary outcome measures, or an extension of the initial intervention study. The proposed mixed method analysis of the does not seem to have been submitted with the trial registration. If the authors have amended the original proposals to ethics. the registered protocol may need to be amended within the Clinical Trial Registry.

- **Response** – We appreciate the reviewer again drawing our attention to some inaccurate and potentially confusing wording in the original submission. Specifically, the description of this as being a nested RCT was inaccurate. The primary and secondary outcomes of the RCT have been reported correctly in the clinical trial registry and in the aforementioned study protocol published in BMJ Open (BMJ open: doi:10.1136/bmjopen-2016-). We have now amended this submitted manuscript to clarify that this is the protocol for the mixed methods process evaluation referred to in the aforementioned trial protocol (BMJ open: doi:10.1136/bmjopen-2016) that reported the primary and secondary outcomes of the RCT. We are neither adding or removing primary or secondary outcomes of the trial, but rather, we are seeking to evaluate processes related to the conduct of the trial and report them openly. It is intended that this will not only assist us, but also the wider readership, in understanding the mechanisms by which the intervention did (or did not) work.

Discussion

The first two lines of the discussion represent repetition.

- **Response:** Thank you for your suggestion, we have modified the text accordingly.

The limitations paragraph: It is unclear what is meant by primary and secondary data will not be collected until six months post-discharge.

- **Response:** Thank you for this clarification, in order to avoid possible prompting of participants to engage in falls prevention strategies during the follow-up period, we wait until 6 months to gather this data (primary and secondary outcomes). We have modified the wording of this in the final paragraph of the Discussion, page 18

References

This protocol paper is perhaps over-referenced. 73 references for a protocol paper may be a little excessive. The authors may wish to reduce the number of references they include in their manuscript. Some of the references are a little dated.

- **Response:** Thank you for your suggestion, we have reduced the number of references accordingly and removed some older references. The total number of references is now 52.